UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF OHIO, COMMONWEALTH OF PENNSYLVANIA, STATE OF ILLINOIS, STATE OF NORTH CAROLINA, and COMMONWEALTH OF VIRGINIA, Plaintiffs, -v- MARTIN SHKRELI, Defendant.	20cv706 (DLC) OPINION AND ORDER

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DENISE COTE, District Judge:

Following a bench trial in this antitrust enforcement action brought by the Federal Trade Commission ("FTC") and seven States,[1] defendant Martin Shkreli was found to have engaged in illegal antitcompetitive conduct. FTC v. Shkreli, No. 20CV00706 (DLC), 2022 WL 135026 (S.D.N.Y. Jan. 14, 2022) ("Shkreli I"). A final judgment entered on February 4, 2022 imposed joint and several liability on Shkreli for the sum of $64.6 million and banned Shkreli for life from participating in the pharmaceutical industry (the "Injunction"). FTC v. Shkreli, No. 20CV00706 (DLC), 2022 WL 336973 (S.D.N.Y. Feb. 4, 2022) ("Shkreli II").

On March 7, Shkreli moved pursuant to Rule 62(d), Fed. R. Civ. P., to stay the Injunction pending appeal. For the following reasons, the motion is denied.

Background

The Findings of Fact and Conclusions of Law from the bench trial are contained in an Opinion of January 14, 2022, which is incorporated by reference (the "Opinion"). Shkreli I, 2022 WL

[1] The seven state plaintiffs are the States of New York, California, Ohio, Illinois, and North Carolina, and the Commonwealths of Pennsylvania and Virginia.

135026, at *1-30. In brief, in October 2014, Shkreli founded Vyera Pharmaceuticals, LLC and its parent company Phoenixus AG ("Phoenixus"; together, "Vyera"). At Shkreli's direction, in August 2015, Vyera acquired the U.S. distribution rights to the brand-name pharmaceutical Daraprim and immediately raised the price of the drug to $750 per pill, an increase of approximately 4,000%. Daraprim is a life-saving drug whose active pharmaceutical ingredient ("API") is pyrimethamine. Pyrimethamine is the gold standard treatment for toxoplasmosis, a rare parasitic infection that can cause severe disease and death. In 2015, Daraprim was the sole-source drug for the treatment of toxoplasmosis.

Vyera implemented a scheme devised by Shkreli to block the entry of generic competition with Daraprim. Vyera's contracts with its distributors and others down the distribution chain severely restricted access to Daraprim in order to prevent generic drug companies from obtaining the quantity of Daraprim, which is the Reference Listed Drug ("RLD") for pyrimethamine, that they needed to conduct the bioequivalence testing required by the Food and Drug Administration ("FDA") for approval of generic pharmaceuticals. Through exclusive supply agreements, Shkreli and Vyera also blocked access to the two most important manufacturers of pyrimethamine. Through these combined strategies, Shkreli successfully delayed the entry of generic

drug competition to Daraprim for at least eighteen months, earning Vyera at least $64.6 million in excess profits. Shkreli I, 2022 WL 135026, at *46-47.

The plaintiffs filed this action on January 27, 2020, bringing claims for violations of §§ 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2, § 5(a) of the FTC Act, 15 U.S.C. § 45(a), and various state statutes against Shkreli, Vyera, Phoenixus, and Kevin Mulleady, former Vyera CEO and member of the Phoenixus Board of Directors. Only Shkreli proceeded to trial; on the eve of trial Vyera and Mulleady settled with both the FTC and the plaintiff States. A bench trial was held from December 14 to December 22, 2021.

The Opinion of January 14, 2022 contains the Findings of Fact and Conclusions of Law from the bench trial. Among other things, the Opinion determined that the market for FDA-approved pyrimethamine was the relevant market for the purpose of antitrust analysis, and that Vyera's restrictive distribution and exclusive supply agreements had an anticompetitive effect on that market. Shkreli I, 2022 WL 135026, at *36-43. The Opinion found Shkreli individually liable for restraint of trade and for monopolizing the FDA-approved pyrimethamine market and jointly and severally liable for the disgorgement of unlawful profits.[2]

[2] The Court ordered the disgorgement of $64.6 million in excess profits and held Shkreli jointly and severally liable for those

Id. at *43-48. Finally, the Opinion found that a lifetime ban on Shkreli's participation in the pharmaceutical industry was warranted. Id. at *45-46.

The Court ordered the plaintiffs to file a proposed judgment and Shkreli to file objections by January 28. On February 4, the Court entered an Order for Permanent Injunction and Equitable Monetary Relief (the "Judgment") and an Opinion addressing Shkreli's objections (the "February 4 Opinion"). Shkreli II, 2022 WL 336973, at *2-3.

Shkreli filed the instant motion to stay the Injunction pending appeal on March 7, and the FTC and the seven States filed opposition on March 28. The motion became fully submitted on April 11.[3]

Shkreli filed a Notice of Appeal from the Judgment on April 5. He is currently incarcerated in the United States Bureau of Prisons Allenwood Correctional Institution located in Allenwood, Pennsylvania, and is due to be released later this year. On April 15, and with Shkreli's consent, his counsel's

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profits, subject to a set-off of any amount paid to the seven States by the settling defendants. Shkreli I, 2022 WL 135026, at *48.

[3] On March 7, Shkreli also moved to stay execution of the $64.6 million in equitable monetary relief. That motion was denied on March 17. FTC v. Shkreli, No. 20CV706 (DLC), 2022 WL 814071 (S.D.N.Y. Mar. 17, 2022) ("Shkreli III").

motion to withdraw was approved. Shkreli is now proceeding pro se.

Discussion

Shkreli has moved to stay the Injunction pending appeal or, in the alternative, to modify the Injunction. Federal Rule of Civil Procedure 62(d) permits a district court to stay an injunction pending the appeal of a judgment. Fed. R. Civ. P. 62(d).

A stay, however, "is an intrusion into the ordinary processes of administration and judicial review." Nken v. Holder, 556 U.S. 418, 427 (2009) (citation omitted). The party requesting a stay therefore bears the burden of showing that the circumstances justify the stay. See New York v. United States Dep't of Homeland Sec., 974 F.3d 210, 214 (2d Cir. 2020) ("DHS").

The standard for evaluating an application for a stay pending appeal is well established. A court should consider:

> (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

SEC v. Citigroup Glob. Markets Inc., 673 F.3d 158, 162 (2d Cir. 2012) ("Citigroup") (per curiam) (citation omitted). The four factors operate as a "sliding scale" where "[t]he necessary

'level' or 'degree' of possibility of success will vary according to the court's assessment of the other stay factors . . . [and] [t]he probability of success that must be demonstrated is inversely proportional to the amount of irreparable injury plaintiff will suffer absent the stay." Thapa v. Gonzales, 460 F.3d 323, 334 (2d Cir. 2006) (citation omitted). In deciding whether to issue a stay, the first two of the factors listed above "are the most critical." DHS, 974 F.3d at 214.

Shkreli has failed to carry his burden to show that a stay of the Injunction or its modification is warranted. With few exceptions, his motion relies upon prior arguments that have been considered and rejected, or on a crimped reading of the factual record.

I. Likelihood of Success on Appeal

Tn support of his application for a stay, Shkreli revives five arguments he has previously raised. Considered separately or together, Shkreli's arguments fail to demonstrate a substantial possibility that he will succeed in vacating the Judgment and its Injunction.

A. Scope of the Injunction

Shkreli contends once more that the Injunction is overbroad, punitive, and vague. Those objections were addressed in the February 4 Opinion and Shkreli raises no new arguments to

cast doubt on its rejection of those objections. See Shkreli II, 2022 WL 336973, at *2-3.

B. Anticompetitive Effects Standard

Shkreli asserts that the Court applied the wrong legal standard to conclude that Vyera's agreements had an anticompetitive effect on the relevant market. These arguments were already addressed in the Opinion. See Shkreli I, 2022 WL 135026, at *42-43.

Shkreli principally contends that the Court failed to hold the plaintiffs to their burden of proof under the standard articulated in Ohio v. American Express Co., 138 S. Ct. 2274 (2018) ("American Express"), to wit, that plaintiffs must show a "substantial foreclosure of competition in the relevant market." Id. at 2284; see also Tampa Elec. Co. v. Nashville Coal Co., 365 U.S. 320, 328 (1961) (applying § 3 of the Clayton Act to exclusive supply agreements in the coal industry). Shkreli argues as he did at trial that American Express raised the standard from that applied in New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015) ("Actavis PLC"). Actavis PLC explained that the relevant test is "whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit". Id. at 656 (citation omitted).

As the Opinion explained, even under Shkreli's rigid view of the law, his scheme "substantially impacted competition in the market for FDA-approved pyrimethamine." Shkreli I, 2022 WL 135026, at *43. Vyera's exclusive supply and restrictive distribution agreements foreclosed generic pharmaceutical companies from acquiring the API and RLD that would otherwise have been "readily available to them in the ordinary course and that were critical to their efforts to compete with Vyera." Id.

To further support this argument, Shkreli misstates the scope of the factual findings in the Opinion. He argues that the Opinion found that Vyera only delayed the entry of two generic drug companies into the FDA-approved pyrimethamine market. Not so. The Opinion found that Vyera's illegal conduct affected at least five generic drug manufacturers, including one of the largest manufacturers of generic drugs in the United States. Id. at *18-27, *47. In connection with the calculation of Vyera's excess profits, however, the trial record only permitted a conservative measure of the length of the delay of entry for two of the five manufacturers. Id. at *47.

C. Evidence of Causation

Shkreli next contends that the Opinion did not adequately consider the extent to which the generic drug companies' own business decisions delayed their market entry. He emphasizes the fact that Vyera did not actually execute its exclusive API

supply contract with its Japanese supplier until after that supplier had already refused to supply pyrimethamine to a generic drug manufacturer. While Shkreli disagrees with the Opinion's findings, the Opinion considered this timeline and the other facts to which he points. See, e.g., id. at *15-16, *20, *42. The trial evidence was overwhelming that it was the defendant's own anticompetitive scheme that was responsible for the delay in the entry of generic competition into the FDA-approved pyrimethamine market. It is not disputed that he intended that outcome. As the Opinion explained, he succeeded in achieving his goal through the scheme he put into operation. Id. at *35.

D. Joint and Several Liability

Shkreli next argues that, pursuant to Liu v. Sec. & Exch. Comm'n, 140 S. Ct. 1936 (2020), he cannot be held jointly and severally liable with Vyera for their violations of the antitrust laws and be held responsible to disgorge its illegally obtained profits. This argument has already been rejected. See Shkreli I, 2022 WL 135026, at *48.

In this motion for a stay, Shkreli emphasizes that the evidence at trial did not show that he received any profit from his investment in Vyera; he took no salary or other compensation from Vyera. While disgorgement may only be ordered for "property causally related to the wrongdoing," the plaintiffs

did not need to show that the illegal gains personally accrued to Shkreli. See SEC v. Contorinis, 743 F.3d 296, 305-06 (2d Cir. 2014) (citation omitted). In any event, Shkreli held the controlling stake in Phoenixus and the scheme that Shkreli devised, managed, and controlled reaped enormous profits for his company. Shkreli I, 2022 WL 135026, at *27-30, *48; see also SEC v. First Jersey Sec., Inc., 101 F.3d 1450, 1476 (2d Cir. 1996) ("First Jersey") ("[T]o the extent that the [liable company's] net worth was increased by its unlawful activities, so was [the individual shareholder's] personal wealth.").

Shkreli argues that First Jersey -- a precedent on which the Opinion relied -- has no bearing on this antitrust case because the First Jersey court was applying § 20(a) of the Securities Exchange Act, which authorizes controlling person liability. 101 F.3d at 1471. On the contrary, First Jersey approved of the imposition of joint and several liability as a proper exercise of the district court's equitable discretion to "fashion appropriate remedies, including ordering that culpable defendants disgorge their profits." Id. at 1474.

E. Relevant Product Market

Finally, Shkreli argues that he is likely to succeed on appeal because the Opinion incorrectly defined the relevant market. He has raised no novel objections unaddressed in the

Opinion and fails again to show a likelihood of success on appeal. See Shkreli I, 2022 WL 135026, at *37-38.

II. Irreparable Harm

Where "likelihood of success [is] totally lacking, the aggregate assessment of the factors bearing on issuance of a stay pending appeal cannot possibly support a stay." Uniformed Fire Officers Ass'n v. de Blasio, 973 F.3d 41, 49 (2d Cir. 2020). At any rate, Shkreli has not met his burden to show that he will be harmed or that any harm to him is irreparable absent a stay of the Injunction.

To demonstrate irreparable harm such that a stay is necessary, a party must show that it will suffer injury which "cannot be remedied" absent a stay. Grand River Enter. Six Nations, Ltd. v. Pryor, 481 F.3d 60, 66 (2d Cir. 2007) (per curiam) (citation omitted). The party seeking the stay has the burden of showing "injury that is not remote or speculative but actual and imminent, and for which a monetary award cannot be adequate compensation." Dexter 345 Inc. v. Cuomo, 663 F.3d 59, 63 (2d Cir. 2011) (citation omitted).

In support of his motion, Shkreli does not identify any actual or imminent irreparable harm that he will experience absent a stay. He does not even address the myriad reasons given in the Opinion in support of the lifetime ban defined in the Injunction, including his failure at trial to express a

clear desire to return the pharmaceutical industry, the breadth of his illegal behavior, and his lack of remorse. Shkreli I, 2022 WL 135026, at *45-46. To the extent Shkreli argues that the Injunction infringes his First Amendment rights, that argument has already been addressed and rejected. Shkreli II, 2022 WL 336973, at *3; see also Nat'l Soc. of Pro. Engineers v. United States, 435 U.S. 679, 697-98 (1978); Peregrine Myanmar Ltd. v. Segal, 89 F.3d 41, 50-52 (2d Cir. 1996). Similarly, he has identified no irreparable harm from the Injunction's requirement that he divest any shares in Vyera that may be returned to him. See Shkreli III, 2022 WL 814071, at *1-2.

III. Injury to Interested Parties

There is a serious risk that, absent the Injunction, Shkreli will reengage in anticompetitive conduct within the pharmaceutical industry and cause injury to interested parties. See, e.g., Shkreli I, 2022 WL 135026, at *46. The burdens of his schemes fell on patients, their families, health care professionals, generic drug manufacturers, and others in the pharmaceutical industry.

Shkreli argues that there is no risk of substantial injury to these parties without a stay because of the passage in 2019 of the Creating and Restoring Equal Access to Equivalent Samples Act (the "CREATES Act"). See 21 U.S.C. § 355-2. The CREATES Act provides a private right of action for generic drug

manufacturers to seek injunctions against pharmaceutical companies that refuse to sell them sufficient RLD on "commercially reasonable, market-based terms" for use in their efforts to obtain FDA approval of generic pharmaceuticals. Id. § 355-2(b)(1). The CREATES Act targets only one leg of the comprehensive scheme Shkreli implemented at Vyera, providing generic drug companies with recourse to the courts to combat a component of the scheme Shkreli perfected. It is a testament to the scale of Shkreli's impact on the industry that he attracted congressional attention and movitated legislative action. Congress's response, however, does not suggest that the risk Shkreli poses to others connected to the generic pharmaceutical industry has been eliminated.

IV. The Public Interest

Finally, the public interest is served by maintaining the Injunction, not by staying it. See Shkreli I, 2022 WL 135026, at *46. Shkreli speculates that the public may benefit should he return to the industry and be able to develop a life-saving drug for a rare disease. That speculation does not override the record developed at trial that Shkreli's engagement in the pharmaceutical industry was not in the public interest. Nor does that record allow for optimism about any engagement with the industry that he may desire in the future. Shkreli's violations of our antitrust laws came at the expense of public

health and undermined public confidence in the government's ability to control notorious predatory behavior within the pharmaceutical industry. For all of these reasons, Shkreli has not shown that the Injunction should be stayed pending appeal.

V. Modification of the Injunction

In the event that his motion for a stay has been denied, Shkreli seeks modification of the Injunction pursuant to Rule 62(d), Fed. R. Civ. P., to prohibit him only from entering into any exclusive supply or restrictive distribution agreements in the United States pharmaceutical industry pending appeal. For the reasons explained above, Shkreli's request for a modification is denied.

Conclusion

Shkreli's March 7 motion to stay or to modify the February 4 Injunction pending appeal is denied. The Clerk of Court shall mail a copy of this Opinion to Martin Shkreli and note service on the docket.

Dated: New York, New York
April 25, 2022

DENISE COTE
United States District Judge